



Improving health outcomes through innovation

ABOUT US

Genesis Research Services is a private clinical trials site offering an extensive range of clinical expertise across a variety of therapeutic areas and phases of clinical trials conduct. We provide sponsors and CROs with a dedicated team of professionals and a purpose-built facility designed to meet the needs and requirements for conducting clinical trials.

STAFF QUALIFICATIONS

- Investigators include specialists in pain medicine, rheumatology, orthopaedic surgery, and gastroenterology/hepatology.
- Core staff include study coordinators, a qualified pharmacist, research assistant, quality coordinator, research governance officer, marketing manager, financial administrator, and medical writer.
- Study coordinators are trained in ECG, venepuncture, FibroScan, dangerous goods handling, physical and mental health first aid, HREC management, CTMS, and electronic site files and source documentation.
- Casual research nurses are available as required.
- Staff trained in social media-based participant recruitment.
- All staff maintain ICH GCP certification and are familiar with applicable regulatory requirements.

FACILITIES & EQUIPMENT

- Dedicated clinical rooms, pathology room, pharmacy, secure stores, offices, waiting area, meeting room, and CRA workspace.
- On-site pharmacy with drug safe and secure storage for IP and devices.
- Vital signs equipment, emergency trolley, ECG, spirometer, ultrasound, and refrigerated centrifuge.
- Temperature-controlled IP storage at ambient, 2-8°C, -20°C and -80°C, with digital monitoring and excursion alerts.
- Contingency procedures for power outages.
- Lockable, alarm-protected on-site storage of trial documents.
- Off-site archiving at a secure storage facility.

POPULATION PROFILE & ACCESS

Newcastle is Australia's 7th largest city, with a population of over 500,000, and a broader catchment of over 800,000 across the Hunter Valley region.

Our participant registry contains over 12,000 potential trial participants. We are affiliated with Hunter Pain Specialists, providing access to an extensive population of patients with a range of acute and chronic pain conditions.

Our site is a 30 minute drive from Newcastle Airport and a short walk from Broadmeadow train station.

LOCATION

Ground Floor, 239-245 Denison Street,
Broadmeadow NSW Australia 2292

t +61 2 4985 1860 f +61 2 4962 2046

reception@genesishresearchservices.com

www.genesishresearchservices.com

THERAPEUTIC EXPERIENCE

- Pain medicine
- Rheumatology
- Neurology
- Gastroenterology
- Neuromodulation
- Vaccines

PARTNERS & AFFILIATIONS

- Pain and gastroenterology clinics.
- Local private hospitals.
- On-site infusion clinic.
- Imaging and pathology providers with research experience.
- Psychologists, psychiatrists, physiotherapists, and ophthalmologists.

QUALITY & ETHICAL ASSURANCE

- GCSA-certified clinical research site.
- Recognised under the NSW Health Quality Recognition Scheme.
- Dedicated research governance officer.
- Study-specific policies and SOPs developed as required.
- Independent ethical review by Bellberry Ltd HRECs.

TIMELINE GOALS

- Full ethical review within 6 weeks.
- Agreements and budgets reviewed and returned same day as received.
- Contract negotiations within 2 weeks.
- Internal governance approvals within 2-3 days.
- Feasibility to recruitment in 8-12 weeks.

ADDITIONAL SERVICES

- Online training provider for ICH GCP and fundamental research knowledge.
- Participant recruitment services.
- Medical writing.